REMARKS

Claims 1-22 are presently pending in the instant Application. In the instant Amendment, Applicants have amended Claims 1, 3, 11, 12, and 14-15, have canceled Claims 2, 7-8, and 16-22, and have added new Claims 23-32. Support for amended Claims 1, 3, 11-12, and 14-15, as well as new Claims 23-32 can be found generally throughout the instant Specification, and particularly on page 1, lines 10-15; and in Claims 1-22 as originally filed. The Examiner has also acknowledged the Information Disclosure Statement submitted on August 27, 2007, and has signed the disclosure statements and placed executed copies in the file. This acknowledgement is appreciated.

The Examiner has also asserted pages 3, 5, and 15 of the instant Specification recite sequences that do not have the required sequence identifier, and has required this defect to be corrected. In response, pages 3, 5 and 13 of the instant Specification have been amended to provide sequence identifiers to these sequences, and a new sequence listing that includes these sequences as well as an executed Statement Regarding Content of Paper and Computer Readable Copies Pursuant to 37 C.F.R. 1.821(f) are filed herewith.

Claim Objections

Claims 1 and 11 have been objected to because, in the Examiner's opinion, they are grammatically incorrect because "...it appears [sic] to be missing the word 'to' between *complementary* and *a* in line 8 of the claim 1 and line 30 of claim 11."

In response, Claims 1 and 11 have been amended to include the word "to" between "complementary" and "a".

The Invention is Definite

Claims 1 and 11 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner has asserted that Claims 1 and 11 recite the dsRNA comprises a sense portion that is complementary [to] a portion of the antisense strand of the target gene". The Examiner believes there is a lack of antecedent basis for "the antisense strand of the target gene" because, in the Examiner's opinion, the target gene is not described as having a sense and an antisense strand. Further, in the Examiner's opinion, it is not clear what is meant by the sense portion of the dsRNA being complementary to antisense strand of the target gene since target genes are not described as having a sense strand and an antisense strand.

Furthermore, the Examiner believes Claims 1 and 11 are further indefinite because the claim recites "the double stranded RNA folds back upon itself". The Examiner believes it is unclear what is meant by the dsRNA folding back upon itself. In the Examiner's opinion, the molecule is already double stranded having a sense and antisense strand that anneal. Hence, the Examiner believes it is unclear how the molecule can then also fold back upon itself. The Examiner has also asserted that, for purposes of prior art, Claim 1 will be interpreted to comprise a target specific dsRNA having a sense and an antisense strand that are complementary to each other.

In addition, Claims 14 and 15 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner has asserted the word "Blasti" recited in Claims 14-15 is not defined in the instant Specification, and as such the "meets [sic]" and bounds of the Claims cannot be determined without assumption. The Examiner then writes "[i]t would appear the word Blasti is an abbreviated form of a marker gene Blasticidin S deaminase but this cannot

accurately be determined without assumption since, in the Examiner's opinion, "Blasti" does not appear to be a common abbreviation of a Blasticidin S deaminase gene.

These rejections are respectfully traversed. With respect to the Examiner's assertion that the phrase "the antisense strand of the target gene" lacks antecedent basis, Claim 1 has been amended to be directed towards, inter alia, a retroviral vector for carrying a target gene specific insert into a cell in order to modify the expression of a target gene having a sense strand and an antisense strand. Support for this amendment can be found on page 1, lines 10-15 of the instant Specification, wherein it is recited:

> Fjose *et al.* have proposed a mechanism for RNA interference [Fjose *et al.* RNA Interference: Mechanisms and Applications. Biotechnology Annual Review, Vol. 7, pp. 10-57 (2001)]. Initially a double stranded RNA sequence (dsRNA) sequence is made available with one strand that is identical or highly similar to a target gene and complementary to an mRNA produced from the transcription of the target gene (the sense strand), and an antisense strand that is complementary to the sense strand.

This passage makes clear that the target gene is double stranded. Moreover, it is respectfully submitted that it is well known to those of ordinary skill in the art that genes are double stranded DNA molecules having a sense strand and an antisense strand.

With respect to the Examiner's assertion that the phrase "the double stranded RNA folds back upon itself" recited in Claims 1 and 11 is indefinite, it is respectfully submitted that the Examiner is incorrect in this regard and that this phrase is indeed definite to one of ordinary skill in the art in light of the instant Specification. In particular, this phrase refers to a portion of the double stranded RNA of a retroviral vector of the instant Invention annealing to another portion of the double stranded RNA of the retroviral vector of the instant Invention that is not

contiguous to the first portion. As a result, the double stranded RNA "folds back" upon itself to form a loop. In particular, on page 3, lines 23-28 of the instant Specification, Applicants clearly state:

> This insert contains AgeI and EcoRI restriction sites. The "20 or more bases" can be either the antisense or sense strand of the double stranded nucleotide sequence of the target gene insert. Naturally, the "21 bases" can also be either the antisense or sense strand. However, ***it is critical that both of these strands are complementary to anneal so that the double stranded RNA folds back upon itself***.

(Emphasis added).

This paragraph makes clear that the nucleotide sequences of "20 or more bases" set forth at line 20 of page 3 anneal to the nucleotide sequences of "21 bases". As a result of this annealing, a loop is formed in the vector. Indeed, Figure 6 is a schematical view of a retroviral vector of the instant Invention wherein the target gene insert double stranded RNA of the vector folds back to form a loop. The loop is clearly shown in Figure 6. Hence, contrary to the Examiner's belief, this phrase clearly definite to one of ordinary skill in the art.

Finally, with respect to the Examiner's assertion that the word "Blasti" recited in Claims 1 and 11 is indefinite, it is respectfully submitted the Examiner's assumption that this term is not a common abbreviation for the blasticidin resistance gene is clearly incorrect. A cursory search of the term "blasti" on the internet resulted in numerous hits wherein "blasti" clearly referred to the blasticidin resistance gene. In support of this position, Applicants attach hereto a copy of the results from Biocompare.com in which the term "blasti" and "gene" were searched. The results were clearly plasmids that contain the blasticidin resistance gene as a reporter gene. Thus, contrary to the Examiner's assertions, the term "blasti" is clearly well known to those of ordinary skill in the art as

referring to the blasticidin resistance gene, and amended Claims 1 and 11, as well as Claims dependent thereto are clearly definite.

For the foregoing reasons, these rejections have been obviated and should be withdrawn.

The Invention is Novel

Claims 1 and 4-6 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Devroe *et al.* (BMC Biotechnology August 2002). The Examiner has asserted the Claims are drawn to a retroviral vector comprising a promoter, a polylinker region, a target gene specific insert comprising a dsRNA having a sense and antisense strand, wherein the sense and antisense strand comprise a length of 19-30, 19-25, or 19-23 nucleotides. In the Examiner's opinion, Devroe *et al.* teach a retroviral vector comprising a U6 promoter, a polylinker sequence and a target gene specific insert sequence, wherein the sequence is capable of forming a hairpin dsRNA (see Figure 1). The Examiner also believes Devroe *et al.* teach the dsRNA is targeted to an NDR gene or a p75 gene wherein each strand is 20 nucleotides in length (see pages 4 and 5). It is the Examiner's position that the instant Specification teaches a polylinker sequence region is a sequence that comprises a plurality of restriction sites, and that a retroviral vector comprising a region having restriction sites flanking the promoter and hairpin dsRNA would constitute a region having a plurality of restriction. Therefore, the Examiner believes the teachings of Devroe *et al.* meet the limitations of the instant Claims.

Furthermore, Claims 1, 4-6 and 10 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Barton *et al.* (PNAS November 2002). The Examiner has asserted the Claims are drawn to a retroviral vector comprising a promoter, a polylinker region, a target gene specific insert comprising a dsRNA having a sense and antisense strand, wherein the sense and antisense

strand each comprise a length of 19-30, 19-25 or 19-23 nucleotides, and wherein said cell has said target gene in its genome. The Examiner contends that Barton *et al.* teach a retroviral vector comprising a promoter, a polylinker sequence and a target gene specific insert sequence wherein the sequence is capable of forming a hairpin dsRNA (see Figure 1). The Examiner also believes that Barton *et al.* teach the dsRNA is targeted to a p53 gene in human 293 cells (see page 14943), which is a gene found in mammalian cells, wherein each strand is 19-21 nucleotides in length (see page 14943 which references Brummelkamp *et al.* who the Examiner believes teach the dsRNA construct, cited as reference 7). It is the opinion of the Examiner that the instant Specification teaches a polylinker sequence region is a sequence that comprises a plurality of restriction sites. It is also The Examiner's belief that Barton *et al.* teach a retroviral vector comprising a region having restriction sites that flanks the hairpin dsRNA, and thus, meets the limitations of the instant Claims.

Furthermore, the Examiner believes U.S. Patent Application No. 2004/0234504 (the '504 application) anticipates Claims 1, 4-7 and 10. In particular, the Examiner has asserted that the instant Claims are drawn to a retroviral vector comprising a promoter, a polylinker region, a target gene specific insert comprising a dsRNA having a sense and antisense strand, wherein the target gene is an oncogene, wherein the sense and antisense strand each comprise a length of 19-30, 19-25 or 19-23 nucleotides and wherein said cell has said target gene in its genome. It is the Examiner's opinion that the '504 application teaches a lentiviral vector comprising a promoter and an siRNA sequence and further comprising nucleotides sequences comprising restrictions sites i.e. polylinker regions (see Figure 1 and claims 1, 2, 6, 10-15 and 18). The Examiner has also asserted the '504 application teaches the lentiviral vector can

comprise pol III promoter such as a U6 promoter instead of a CMV promoter (see Figure 10 and paragraph 0058), that the siRNA comprises strands of 19-22 nucleotides in length (see paragraph 0038), and that the siRNA can target cancer genes and transcripts of malignant conditions (see paragraph 0017-0018).

Applicants respectfully traverse these rejections. Devroe *et al.* teach a vector targeted to an NDR gene or p75 gene comprising *inter alia*, the U6 promoter. However, amended Claim 1 is directed towards, *inter alia*, a retroviral for carrying a target gene specific insert into a comprising a U6 promoter having sequence of:

ttcccatgattccttcatatttgcatatacgatacaaggctgttagagagataattagaattaatttgactgtaaacacaaagatattagtacaaaat acgtgacgtagaaagtaataatttcttgggtagtttgcagttttttaaaattatgttttaaaatggactatcatatgcttaccgtaacttgaaagtatttc gatttcttgcctttatatatcttgtggaaaggacgaaacaccg (SEQ ID NO:7)

Thus, as the Examiner has clearly admitted in making this rejection, Devroe *et al.* teach such vector, and this rejection should be withdrawn

Similarly, in rejecting Claims 1, and 4-6 in light of the teachings of the Barton *et al.*, the Examiner has admitted Barton *et al.* do not teach a vector as claimed in amended Claim 1. Hence, the rejection of amended Claim 1, as well as Claims dependent thereto in light of the teachings of Barton *et al.* has been obviated, and the rejection should be withdrawn.

With respect the Examiner's rejection of Claims 1, 4-7 and 10 in light of the Examiner's interpretations of the teachings of the '504 application, it is initially noted that Claim 7 has been canceled, without prejudice. Hence, the rejection of Claim 7 is MOOT. With respect to the rejections of Claims 1, 4-6 and 10, it is again noted that in making this rejection, the Examiner has admitted that the '504 application does not teach a retroviral vector of amended Claim 1.

Thus, this rejection is obviated, and the rejection of Claim 1 as amended, as well as of Claims dependent thereto should be withdrawn. In addition, new Claims 23, 27 and 31, as well as Claims dependent thereto are also clearly novel in light of the teachings of Devroe et al. and Barton et al., and should be allowed to issue.

The Invention is Nonobvious

Claims 1, 2, 4-7 and 9-11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Devroe *et al.* (discussed above), US Patent 5,624,803 (the '803 patent) and Chang *et al.* (Current Gene Therapy, 2001, 1: 237-251). The Examiner has asserted the instant Claims are drawn to a retroviral vector comprising a promoter, a polylinker region, a target gene specific insert comprising a dsRNA having a sense and antisense strand, wherein the promoter is a U6 promoter sequence of SEQ ID No. 7, wherein the polylinker region comprises a nucleotide sequence of SEQ ID NO. 4, wherein the sense and antisense strand each comprise a length of 19-30, 19-25 or 19-23 nucleotides, wherein the target gene is an oncogene, wherein the retroviral vector is a modified Lentivirus comprising a RRE and a U6 promoter of SEQ ID No. 7, wherein said cell has said target gene in its genome, wherein the Lentivirus further comprises a Blasti reporter gene.

The Examiner has also asserted Devroe *et al.* teach a retroviral vector comprising a U6 promoter, a polylinker sequence and a target gene specific insert sequence wherein the sequence is capable of forming a hairpin dsRNA (see Figure 1), and that the dsRNA is targeted to an NDR gene or a p75 gene wherein each strand is 20 nucleotides in length (see pages 4 and 5). It is the Examiner's opinion that the instant Specification teaches a polylinker sequence region is a sequence that comprises a plurality of restriction sites. It is also the Examiner's opinion that a

retroviral vector comprising a region having restriction sites flanking the promoter and hairpin dsRNA would constitute a region having a plurality of restriction sites. Hence, the Examiner has taken the position that such a vector meets the limitations of the instant claims. However, the Examiner has admitted that Devroe *et al.* do not specifically teach a U6 promoter sequence of SEQ ID No. 7, and do not teach using lentiviral vectors wherein the CMV promoter is removed and a REV element is present.

Furthermore, the Examiner has asserted the '803 patent teaches a U6 promoter sequence and efficient expression of nucleic acids using a promoter described therein. However, the Examiner has also admitted that the '803 patent does not teach the promoter sequence of SEQ ID NO: 7 of the instant Application because the promoter sequence of the '803 patent has one nucleotide mismatch as compared to the instantly claimed sequence. Despite this difference in sequences however, it is the Examiner's opinion that this nucleotide mismatch in the instantly claimed sequence does not render the U6 sequence of SEQ ID NO:7 and its use in a retroviral vector of the instant Invention patentably distinguishable over the sequence taught by the '803 patent, absent evidence to the contrary.

In addition, the Examiner believes Chang *et al.* teach the use of lentiviral vectors as an efficient gene delivery vehicle and teach lentiviral vectors are advantageous over similar vectors systems in that they can infect non-dividing cells (see page 237). The Examiner has also asserted that Chang et al. teach "...all lentiviral vectors need the REV element that interacts with the REV-response element for efficiently [sic] cytoplasmic transport in cells (see page 240-241)."

In light of the Examiner's interpretations of the teachings of the references discussed above,

the Examiner believes it would have been obvious to one of skill in the art to use a lentiviral vector to express dsRNA as taught by Devroe *et al.* Moreover, the Examiner has asserted it would have been further obvious to one of skill in the art to use U6 promoter instead of the CMV promoter in a lentiviral vector and to incorporate an REV element as taught by Chang *et al.*

Furthermore, Claims 1, 2, 4-7 and 9-11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of published US 2004/0234504 (the '504 application), US Patent 5,624,803 (the '803 patent) and Chang *et al.* (Current Gene Therapy, 2001, 1: 237-251). The Examiner contends the instant Claims are drawn to a retroviral vector comprising a promoter, a polylinker region, a target gene specific insert comprising a dsRNA having a sense and antisense strand, wherein the promoter is a U6 promoter sequence of SEQ ID No. 7, wherein the polylinker region comprises a nucleotide sequence of SEQ ID NO. 4, wherein the sense and antisense strand each comprise a length of 19-30, 19-25 or 19-23 nucleotides, wherein the target gene is an oncogene, wherein the retroviral vector is a modified Lentivirus comprising a RRE, a U6 promoter of SEQ ID No. 7, wherein said cell has said target gene in its genome, wherein the Lentivirus further comprises a Blasti reporter gene.

It is the Examiner's belief that the '504 application teaches a lentiviral vector comprising a promoter and a siRNA sequence and further comprising nucleotide sequences comprising restrictions sites i.e. polylinker regions (see Figure 1 and claims 1, 2, 6, 10-15 and 18), that the lentiviral vector can comprise a pol III promoter such as a U6 promoter instead of a CMV promoter (see Figure 10 and paragraph 0058), that the siRNA comprises strands of 19-22 nucleotides in length (see paragraph 0038), and that the siRNA can target cancer genes and transcripts of malignant conditions (see paragraph 0017-0018). The Examiner has admitted

that the '504 application does not specifically teach a U6 promoter sequence of SEQ ID No. 7, and also does not teach a lentiviral vector comprising an REV element.

The Examiner has also asserted the '803 patent teaches a U6 promoter sequence and efficient expression of nucleic acids using this promoter. The Examiner has admitted that the promoter sequence taught by the '803 has one nucleotide mismatch as compared to the instantly claimed sequence (see included sequence alignment), but in the Examiner's opinion, this nucleotide mismatch in the instantly claimed sequence does not render the U6 sequence and its use in an expression vector patentably distinguishable over the sequence taught by the '803 patent absent evidence to the contrary.

The Examiner has also asserted Chang *et al.* teach the use of lentiviral vectors as an efficient gene delivery vehicle and teach lentiviral vectors are advantageous over similar vectors systems in that they can infect non-dividing cells (see page 237). The Examiner also believes Chang *et al.* teach all lentiviral vectors need the REV element that interacts with the REV-response element for efficiently cytoplasmic transport in cells (see page 240-241).

It is the opinion of the Examiner that it would have been obvious to one of skill in the art to use the U6 promoter taught by the '803 patent and to incorporate a REV element as taught by Chang *et al.* Furthermore, the Examiner contends one of skill in the art would have wanted to use the U6 promoter sequence taught by the '803 patent, given that the '803 patent teaches use of said promoter efficiently drives expression of oligonucleotides in cells. The Examiner has also asserted Chang *et al.* teach that for efficient cytoplasmic transport of the lentiviral vector in cell, the REV element needs to be present in the vector to allow the REV/RRE interaction to occur; therefore one of skill in the art would have been motivated to incorporate a

REV element into a lentiviral vector.

The Examiner also believes one would have expected success at using the U6 promoter taught by the '803 patent for expression of a siRNA given that, in the Examiner's opinion, the '803 patent teaches efficient expression of a oligonucleotide expressed from a vector comprising a U6 promoter. The Examiner further believes one would have expected to be able to use a lentiviral vector comprising a REV element for delivery of a dsRNA given that, in the Examiner's opinion, Chang *et al.* teach said vectors are well known to be efficient gene delivery vehicles and the REV element is essential for cytoplasmic transport.

Thus in the absence of evidence to the contrary, it is the position of the Examiner that the instant Invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicants respectfully traverse these rejections. With respect to the Examiner's rejections of Claims 2 and 7, these Claims have been canceled, without prejudice. Hence, the rejections of these Claims are MOOT. Furthermore, in making these rejections, even though the Examiner has admitted that no reference cited in this office action teaches SEQ ID NO:7, the Examiner believes the difference between SEQ ID NO:7 and the sequence disclosed in the '803 patent does not render the U6 sequence and its use in an a retroviral vector of the Instant Invention patentably distinguishable over the sequence taught by the '803 patent absent evidence to the contrary. However, the Examiner has not provided any evidence in support of this statement. The Federal Circuit has specifically stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441

F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR International v. Teleflex*, Inc., 550 U.S. at ___ , 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). Hence, contrary to the Examiner's assertions, the use of SEQ ID NO:7 in a retroviral vector of the instant Invention is not obvious to one of ordinary skill in the art.

Furthermore, contrary to the Examiner's assertion that Chang *et al.* teach all lentiviral vectors need the REV element, which interacts with the REV-response element for efficient cytoplasmic transport in cells, Chang *et al.* teach the REV element is ***not*** necessary. Indeed, on page 241, Chang *et al.* specifically state:

> To overcome the requirement of Rev in HP, simultaneous silent mutations of multiple CRS or INS sites have to be introduced into the gag-pol reading frame to allow efficient RNA export out of the nucleus (Schneider et al., 1997). Alternatively, Rev-RRE function may be partially replaced with the constitutive transport element (CTE) of the Mason-Pfizer monkey virus (MPMV) (Bray *et al.*, 1994).

The Examiner has also asserted that the '504 application teaches a lentiviral vector that comprises a pol III promoter such as a U6 promoter instead of a CMV promoter, that siRNA comprises strands of 19-22 nucleotides in length, and that siRNA can target cancer genes and transcripts of malignant conditions. However, as explained above, the Examiner has admitted the '504 application teaches neither a U6 promoter sequence of SEQ ID NO:7, nor a lentiviral vector comprising an REV element.

In the instant Application, Claim 1 has been amended to be directed towards, *inter alia*, a retroviral vector for carrying a target gene specific insert into cell, comprising a promoter having a nucleotide sequence of SEQ ID NO:7. It is respectfully submitted that, contrary to the Examiner's assertions, there is no motivation or suggestion in any of the references the Examiner

has cited to combine their respective teachings as the Examiner has done in making these rejections. On the contrary, it appears Applicants' disclosure provided such motivation in making this rejection. However, the Examiner cannot rely on impermissible hindsight to arrive at a determination of obviousness. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). The Court of Appeals for the Federal Circuit has stated that "selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the Applicant's disclosure." *Interconnect Planning Corporation v. Feil.*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985)]. *In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988). Hence, these rejections are obviated and should be withdrawn.

Furthermore, in light of the rejections the Examiner has made in the outstanding office action, and the Examiner's admission that SEQ ID NOS:4 and 8 are free of the prior art searched and made of record, new Claims 23, 27, and 31 as well as Claims dependent thereto, are also clearly novel and nonobvious, and should be allowed to issue.

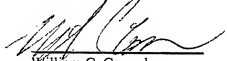
Fees

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account no. 18-1982 for any underpayment, or to credit any overpayments.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,



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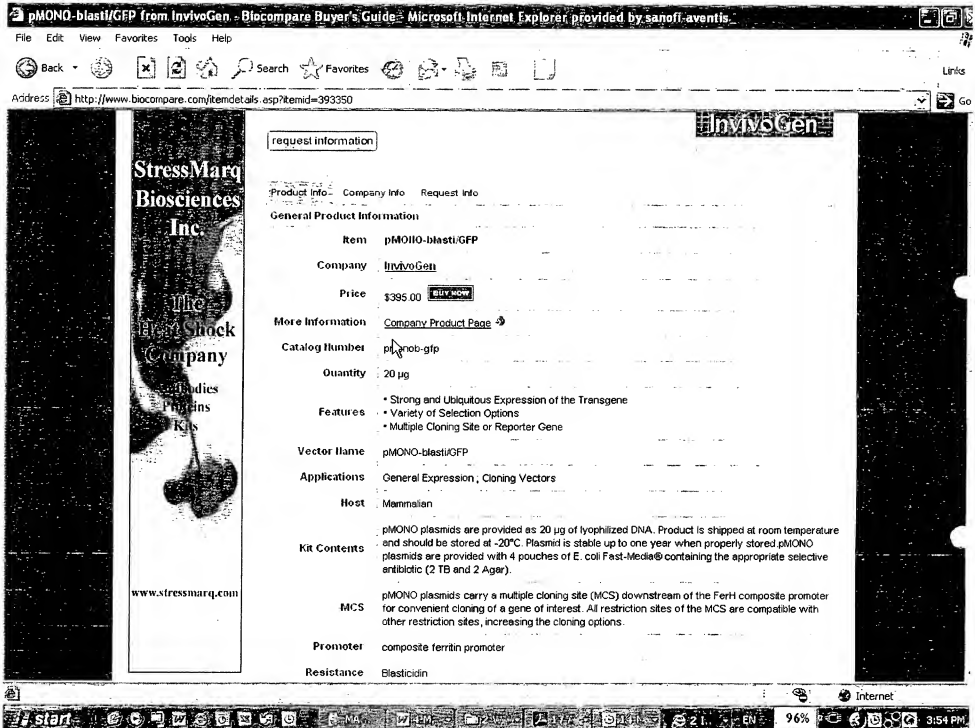
DOCKET NUMBER: USAV 2002/0187 US PCT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request information
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Product Info Company Info Request Info
General Product Information
Item pMOlIO-blasti/GFP
Company InvivoGen
Price $395.00 BUY NOW
More Information Company Product Page
Catalog Number pl nob-gfp
Quantity 20 µg
Features • Strong and Ubiquitous Expression of the Transgene
• Variety of Selection Options
• Multiple Cloning Site or Reporter Gene
Vector Name pMONO-blasti/GFP
Applications General Expression ; Cloning Vectors
Host Mammalian
Kit Contents pMONO plasmids are provided as 20 µg of lyophilized DNA. Product is shipped at room temperature and should be stored at -20°C. Plasmid is stable up to one year when properly stored.pMONO plasmids are provided with 4 pouches of E. coli Fast-Media® containing the appropriate selective antibiotic (2 TB and 2 Ager).
MCS pMONO plasmids carry a multiple cloning site (MCS) downstream of the FerH composite promoter for convenient cloning of a gene of interest. All restriction sites of the MCS are compatible with other restriction sites, increasing the cloning options.
Promoter composite ferritin promoter
Resistance Blasticidin
StressMarq Biosciences Inc.
The Heat Shock Company
Antibodies
Proteins
Kits
www.stressmarq.com
Internet
start
96%
3:54 PM